## REMARKS

This amendment and argument are filed as a complete response to the Office Action mailed on April 10, 2006. Claims 1 – 24 are pending in the application. Claims 1 and 10 – 21 are rejected. Objection has been raised to the Specification and to claims 15 and 16. Claims 2 – 9 and 22 – 24 have been withdrawn. Reconsideration is requested in view of the above amendments and the remarks which follow.

### I. THE RESTRICTION REQUIREMENT

In the subject office action the outstanding restriction requirement was made final. The examiner has concluded that a "special feature" which links the claims of Groups I - IV is known in the art and therefore the claims of the differing groups lack unity, i.e., the inventions do not form a general inventive concept. Applicant must again traverse the basis for this conclusion, as the Lu reference does not at all disclose or suggest

> "[testing] for only one analyte, wherein each test strip comprises a detection of a different concentration of the analyte in order to establish a semi-quantitative analysis (see claims 1 and 2 in particular)." [Office Action, page 2.]

The above-quoted language is no more than a failed effort to find Applicant's disclosed invention in the prior art. There is simply no support in the Lu patent to interpret claims 1 or 2 of the Lu patent in this manner. Furthermore, a careful reading of claim 2 in the Lu patent confirms that subsections (a), (b) and (c) at most refer to "each of the test strips" individually and there is no suggestion that "the device [of Lu] can be utilized ... wherein each test strip comprises a detection of a different concentration of the analyte in order to establish a semi-quantitative analysis ... [Page 2 of the Office Action]" Although claim 2 of Lu discloses "semiquantitative, analysis" this is only claimed in the context of a single test strip and therefore cannot be based on any combination of test strips.

For the above reasons it cannot be said that the method of Group I lacks unity with the claims in the other Groups. In fact, based on the above analysis of the Lu reference, and the criteria of the PCT Rules 13.1 et seq., the examiner must now agree that all of the claims do share a common technical feature (see, again, generic claim 22) and all of the claims do form a general inventive concept. That is, the claimed devices are specific to performing the method set forth in the claims of Group I. Because the restriction requirement is technically deficient, it is again respectfully requested that the examiner withdraw the requirement.

## II. CONTENT OF SPECIFICATION AND OBJECTION TO THE CLAIMS

The specification has been amended to conform with the requirements presented in the office action. The specification has also been amended to correct various informalities or errors of an apparent nature. Claims 15 and 16 have been amended per the examiner's suggestion to provide more express consistency with language of claim 10 from which each depends.

## III. THE REJECTIONS UNDER 35 USC 112

Claims 1, 10 – 13 and 20 were rejected under Section 112. For reasons explained below, the rejection relating to claim 1 is traversed in part. Amendments fully responsive to the other Section 112 rejections have been made. The office action rejected claim 1 because the recitation "sufficient to induce a response" was found to be unclear as to what type of "response" is created to indicate the "sufficient" level of analyte. Applicant submits that to satisfy the requirements of Section 112 it is not necessary to amend the claims to expressly recite details of example embodiments presented in the Specification. On the other hand, applicant may refer to the detailed description and to example embodiments in order to demonstrate that the subject language is well understood in view of the detailed description. In this regard, note page 6 of the Specification, which states:

> "although formation of an immunocomplex is disclosed as a means for indicating presence of the targeted species within one of multiple test ranges, other ligand recognition systems will be suitable depending on the chemicals involved and specific test goals. Detection is commonly, but not exclusively, effected by, first, the association of a detector reagent with a capture reagent, typically in a membrane. The reagents may be synthetic constructs or may be derived from natural sources."

See, also, the following text found at pages 6 and 7 of the Specification:

> With regard to the monitoring of hCG levels, i.e., concentrations, one methodology according to the invention is based in part on a well known technique for detecting the presence of hCG. This methodology begins with allowing the source sample to begin a lateral flow through a fibrous medium to a first zone formed of porous material (commonly termed a conjugate pad area). The first zone contains an appropriate labelled detector reagent. Interaction between the detector reagent and target species present in the source sample results in an association between the two molecules. Subsequently this antigen-antibody complex is carried by the source sample to a second zone, formed on a membrane and referred to as a testing area. Flow through the membrane is essentially lateral and unidirectional. Conventionally, a predefined region along the surface of the testing area, referred to as the capture zone contains a species of immobile antibodies which

also associate with the target species in the antigen-antibody complex to form an antigen-antibody-antigen complex.

Once formed, this sandwhich complex remains in a relatively a stable position within the capture zone. When a sufficient number of sandwhich complexes are formed in the capture zone, their presence in the capture zone is visually detectable. With a sufficient quantity of sandwhich complexes present in the capture zone, it is possible to visually determine whether some threshold concentration of the target species, hCG, is present in the source sample. The ability to detect the mere presence of the target species in the sample is dependent on the sensitivity of the control zone to develop a detectable signal in response to the presence of the analyte. In the examples described, the signal is visually detectable, but, more generally, the capture zone may produce any kind of detectable signal.

As illustrated for example embodiments, text at page 8, lines 8 – 12 identifies an example form of response within the scope of claim 1, i.e, "a visible change along one or more assay regions according, for example, to an immunologic reaction."

Based on the above citations it is respectfully submitted that the phrase in claim 1, "sufficient to induce a response" when read in view of the detailed description is of sufficient clarity to satisfy the requirements of Section 112.

## IV. REJECTIONS UNDER SECTION 102 BASED ON BOEHRINGER (WO 98/39657)

Claims 10 – 16 and 19 – 21 were rejected under Section 102 based on Boehringer et al. This rejection is premised on a conclusion that at least each of claims 10 and 20 can be read upon the Boehringer reference. In fact, they cannot be read upon this reference. It is noted, to more clearly distinguish over the prior art, claim 10 has been amended to specify that the second sample is brought into contact with the second unit to indicate whether analyte is present "in the second sample" at at least the second level. With respect to claim 10, the reference does not teach or suggest the novel combination of the following steps:

providing a first sample from the source ...

bringing the first sample into contact with the first unit ... to indicate whether analyte is present in the sample at at least the first level ...

providing a second sample from the source **on an occasion subsequent to providing the first sample** ...

bringing the second sample into contact with the second unit to indicate whether analyte is present in the second sample at at least the second level [Emphasis Added].

Although the rejection cites numerous passages and examples from the reference, none of these, alone or in combination, teach or suggest

> providing a first test unit...
>
> providing a second test unit ...
>
> providing a first sample from the source ...
>
> bringing the first sample into contact with the first unit ... to indicate whether analyte is present in the sample at at least the first level ...
>
> providing a second sample from the source on an occasion subsequent to providing the first sample ...
>
> bringing the second sample into contact with the second unit to indicate whether analyte is present in the second sample at at least the second level.

For these reasons the claimed subject matter is novel and non-obvious. It is requested that the rejection of claim 10 under Section 102 be withdrawn.

Claim 20 is distinguished over the Boehringer reference for reasons similar to those described with regard to claim 10. Specifically, claim 20 requires the following feature:

> ... on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels.

Allowance of claim 20 is requested.

## V. REJECTIONS UNDER SECTION 102 BASED ON KENJYOU (US 2004/0096985)

The Kenjyou reference has been applied to claims 10, 19 and 20, but this reference does not anticipate or suggest the claimed invention. Applicant notes that the reference uses language such as "a plurality of units" (see paragraph 0059) while the rejected claims use language such as "first test unit" and "second test unit." It is understood that devices of the Kenjyou reference comprise multiple units, while applicant's inventive methods relate to multiple units of test devices. See, for example, the disclosure at page 10 of the Specification, which states:

> Multiple units of such devices may be provided in kit form to repeatedly perform assays of different samples from one or multiple sources in order to monitor and compare concentrations among sources or among samples from the same source.

Thus, the "first test unit" and "second test unit" of claim 10, and the "two or more test units" of claim 20 mean multiple, separate devices. For example, in claim 10, the first region of the first test unit is on a different device than the first region of the second test unit. Any effort to read this language on the Kenjyou reference would be inconsistent with applicant's teachings presented in the detailed description.

Moreover, each of the claims 10 and 20 includes further distinctions which also render the Kenjyou reference deficient. Specifically, the reference fails to disclose or suggest providing a "first sample from the source" and providing a "second sample from the source on an occasion subsequent to providing the first sample ..." as required by claim 10. Claim 10 uniquely requires the combination of:

> providing a first sample from the source ...
>
> bringing the first sample into contact with the first unit ... to indicate whether analyte is present in the sample at at least the first level ...
>
> providing a second sample from the source on an occasion subsequent to providing the first sample ... [and]
>
> bringing the second sample into contact with the second unit to indicate whether analyte is present in the second sample at at least the second level.

Claim 20 is also distinguished over the Kenjyou reference, requiring:

> ... on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels.

None of the disclosure of the Kenjyou reference teaches or suggests the features of claims 10, 19 or 20.

For all of these reasons the rejection of claims 10, 19 and 20 under Section 102 based on the Kenjyou reference is in error and withdrawal is requested.

## VI. REJECTION OF CLAIM 1 UNDER SECTION 103 BASED ON BOEHRINGER (WO 98/39657) OR KENJYOU (US 2004/0096985) IN VIEW OF TORANTO ET AL. (US 2003/0175992)

The rejection of claim 1 is premised on at least two incorrect interpretations of the primary references presented at pages 11 and 12 of the office action:

(i) that the Boehringer reference and/or the Kenjyou reference teach "providing multiple test devices" and

(ii) that the Boehringer reference and/or the Kenjyou reference teach "bringing a different sample from the source into contact with a second of the test devices."

The office action also confirms at page 12 that both references fail to teach the monitoring of temporal changes in analyte levels.

The office action describes the Toranto reference as disclosing a "test system" with a "multiplicity of test units." However, the "test units" of Toranto do not meet the requirements of applicant's "test devices." Applicant claims a method in which each "test device" includes "a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source ..."

This method is quite different and non-obvious over the combination of prior art references. By way of example, the Toranto reference describes, with reference to FIGS 3 and 4, a compartment 44 that holds "multiple assay tests ..." See par. 0132. See, also, FIGS 1 and 2, which disclose an individual "assay test" as comprising "a base 16, a middle 20 and a top 21. None of the embodiments of Toranto are consistent with applicant's devices each "including a plurality of regions, each region responsive at a different sensitivity level ..."

There is no combination of prior art references which results in the invention defined applicant's claim 1. To further distinguish the subject matter of the claimed method, claim 1 has been amended to more expressly recite this distinction. That is, the amended claim now states:

> providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source ...

Indeed, all of applicant's disclosed devices (e.g., see figures 1 – 9) are unitary structures comprising multiple regions each "responsive at a different sensitivity level ..."

None of the art of record teaches or suggests even a single "unitary test device including a plurality of regions, each region responsive at a different sensitivity level ..."

Only the applicant teaches multiple of such unitary devices to monitor temporal changes by

> subsequently bringing a different sample from the same source into contact with a second of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the second unitary test device ...

There is no teaching in the prior art to modify the references to meet the terms of claim 1. Any effort to reconstruct the primary and secondary references to meet the terms of claim 1 would be in hindsight and without suggestion and would be inconsistent with the disclosures presented in the references.

For these reasons claim 1 is distinct and non-obvious over the prior art. Allowance is requested.

## VII. REJECTION OF CLAIMS 17 AND 18 UNDER SECTION 103 BASED ON BOEHRINGER (WO 98/39657) IN VIEW OF COLE (US 6,656,745)

Reconsideration of the rejection of claims 17 and 18 is requested in view of the above argument concerning claim 10, 15 and 16 from which they each depend. Further, it is suggested that the combination required to meet the terms of these claims is a hindsight reconstruction of the prior art.

## CONCLUSIONS

All objections to the specification and claims have been addressed. All claims are now fully distinguished over the art of record and, based on the above reasons, it is submitted that the application now fully complies with the requirements under Sections 112, 102 and 103. It is believed that the application is now in condition for allowance and allowance is requested.

Respectfully submitted,

Ferdinand M. Romano 10 July 2006

Ferdinand M. Romano Date
Reg. No. 32,752
Beusse Wolter Sanks Mora & Maire, P.A.
390 N. Orange Avenue, Suite 2500
Orlando, FL 32801
(407) 926-7722

CERTIFICATE OF TRANSMISSION

I HEREBY CERTIFY that this Response To Office Action is being FAXED to the U.S. Patent Office at 571-273-8300 (Central Fax Number) on this 10th day of July, 2006.

Ferdinand M. Romano

Ferdinand M. Romano